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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,909	06/29/2000	Ronald J. Pettis	P-4901	7814

7590

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EXAMINER

TRAN, BINH Q

ART UNIT

PAPER NUMBER

3748

DATE MAILED: 04/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/606,909

Applicant(s)

PETTIS ET AL.

Examiner

BINH Q. TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 17-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election / Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I.* Claims *1-16*, drawn to *a method for delivering a substance into skin* classified in class *604*, subclass *500*.
- II.* Claims *17-24*, drawn to *a needle for intradermal delivery of a substance into skin*, classified in class *604*, subclass *264*.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method for delivering a substance into skin (I) can be used without using needle such as needle-free or pressure injection method; or the needle (II) can be used for delivery any substance into human or animal body such as intramuscular, intravenous, subcutaneous.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Eric M. Lee (Reg. No. 30,471) on April 02, 2002 a provisional election was made without to prosecute the invention of I, claims 1-16. Affirmation of

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this election must be made by applicant in replying to this Office Action. Claims 17-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

The subject matter of this application admits of illustration by a drawing to facilitate understanding of *an apparatus of the invention*. Applicant is required to furnish *a drawing of the apparatus* under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically,

-In claim 6, line 1, "*a hormone is delivered*" is unclear.

The claims not specifically mentioned are indefinite since they depended from one of the above claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-16 are rejected under 35 U.S.C. 102 (e) as being clearly anticipated by Gross et al. (Gross) (Patent Number 5,848,991).

Regarding claims 1-9, and 16, Gross discloses a method for delivering a substance into skin comprising delivering the substance into an intradermal space within the skin through a small gauge needle inserted into the intradermal space, wherein an outlet of the needle is inserted at a depth within the skin such that leakage of the substance to the surface of the skin is substantially prevented; wherein the needle is selected from the group consisting of microneedles, catheter needles, and injection needles; wherein a single needle is inserted; wherein multiple needles are inserted; wherein the substance is a liquid delivered by pressure directly on the liquid; wherein a hormone, which is selected from the group consisting of insulin and PTH, is delivered (See Figures 1-13; col. 3, lines 9-68; cols. 4-6, lines 1-68; col. 7, lines 1-21).

Regarding claims 10-15, Gross further discloses wherein the outlet is at a depth of about 500 μ m to 2 mm when the needle is inserted into the skin, and needle is about 300 μ m to 2 mm long (See Figures 1-13; col. 3, lines 9-68; cols. 4-6, lines 1-68; col. 7, lines 1-21).

Claims 1-5, and 8-16 are rejected under 35 U.S.C. 102 (b) as being clearly anticipated by Cirelli et al. (Cirelli) (Patent Number 4,886,499).

Regarding claims 1-5, 8-9, and 16, Cirelli discloses a method for delivering a substance into skin comprising delivering the substance into an intradermal space within the skin through a small gauge needle inserted into the intradermal space, wherein an outlet of the needle is inserted at a depth within the skin such that leakage of the substance to the surface of the skin is substantially prevented; wherein the needle is selected from the group consisting of microneedles, catheter needles, and injection needles; wherein a single needle is inserted; wherein multiple needles are inserted; wherein the substance is a liquid delivered by pressure directly on the liquid (See Figures 1-8; col. 3, lines 45-68; cols. 4-6, lines 1-68; col. 7, lines 1-20).

Regarding claims 10-15, Cirelli further discloses wherein the outlet is at a depth of about 500 μ m to 2 mm when the needle is inserted into the skin, and needle is about 300 μ m to 2 mm long (See Figures 1-8; col. 3, lines 45-68; cols. 4-6, lines 1-68; col. 7, lines 1-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cirelli in view of Cheikh.

Regarding claims 6-7, Cirelli discloses all the claimed limitation as discussed above except the substance is a hormone, which selects from the group consisting of insulin and PTH.

Stout teaches that it is conventional in the art, to use a needle to inject hormone, which selects from the group consisting of insulin and PTH, into a human or animal body (See col. 12, lines 56-68; cols. 13-16, lines 1-68).

It would have been obvious to one having ordinary skill in the art at the time the invention was made, to use a needle to inject hormone into a human or animal body of Cirelli, as taught by Cheikh for the purpose of for delivery of drug into the bloodstream, and controlling the amount of drug absorbs into a patient's body, so as to increase the efficiency of drug during treatment of patient.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and consists of five patents:

Gross et al. (Patent Number 5997501), D'Antonio et al. (Patent Number 6056716), Stout et al. (Patent Number 6319224), Cirelli et al. (Patent Number 5848990), and Magnet (Patent Number 5279552) all discloses an intradermal injection method and apparatus for delivering a substance into a body.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Binh Tran whose telephone number is (703) 305-0245. The examiner can normally be reached on Monday-Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas E. Denion, can be reach on (703) 308-2623. The fax phone number for this group is (703) 746-4561.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0861.

BT
April 20, 2002



Binh Tran
Patent Examiner
Art Unit 3748



THOMAS DENION
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700